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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,649	08/01/2000	DANIEL LADANT	03495.0190	8848

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,649

Applicant(s)

LADANT ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-15,17-22,25-29,31,32,34-38,46-59,61-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,13-15,17-22,25-29,31,32,34-38,46-59,61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 3-25-2004 are acknowledged. Claims 10, 13-15, 17, 20-21, 25-28, 31-32, 36, 46, 48, 52 and 54 have been amended. Claims 12 and 30 have been canceled. Claims 63-64 have been added. Claims 10-11, 13-15, 17-22, 25-29, 31-32, 34-38, 46-59 and 61-64 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 10-22, 46-51 and 58 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite as the lack essential steps is withdrawn in light of the amendment thereto.

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “triggering transcriptional activation” is withdrawn in light of the amendment thereto.

The rejection of claims 15 and 32 under 35 U.S.C. 112, second paragraph, as being for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “binding between the molecule of interest and the target ligand is detected by signal amplification that triggers transcriptional activation and is **quantified by measuring the synthesis of a signaling molecule or expression of a reporter gene**” is withdrawn in light of the amendment thereto.

The rejection of claims 20 and 36 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "protein with a selectable phenotype" is withdrawn in light of the amendment thereto.

The rejection of claims 25-32, 34-38, 52-57, 59 and 61-62 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite as they lack essential steps is withdrawn in light of the amendment thereto.

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "triggering or abolishing transcriptional activation" is withdrawn in light of the amendment thereto.

The rejection of claims 46 and 52 under 35 U.S.C. 112, second paragraph, for reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claims 48 and 54 under 35 U.S.C. 112, second paragraph, for lacking proper antecedent basis the limitation "the reporter gene encodes resistance to an antibiotic" in line 2 is withdrawn in light of the amendment thereto.

New Objections

Claim 17 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

Claim Rejections Maintained and New Grounds of Rejection***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 10-15, 17-22, 25-32, 34-38 and 46-59 and 61-62 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-23 and 24-38 of copending Application No. 09/973013 is maintained for reasons of record. Applicant indicated that they intend to let this application go to allowance thereby obviating said rejection. The instant rejection will only be withdrawn when the instant claims are in condition for allowance **and** none of the cited claims in the copending application have been allowed. As stated previously, although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of selecting a molecule of interest that can bind to a target ligand (or identifying a substance that modulates said binding) utilizing signal amplification system comprising a bacterial multi-hybrid system

utilizing enzyme fragments and/or enzyme modulators to detect protein-protein interactions.

The instant claims are also drawn to methods wherein said selection is done in a bacterium.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11, 13-15, 17-22, 25-29, 31-32, 34-38, 46-59 and 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 14 and 27 are rendered vague and indefinite by the use of the phrase “chosen from adenylate cyclase or guanylate cyclase and a modulating substance” is maintained for reasons of record. The amendment to said claims is insufficient to overcome the rejection as step (B) recites “a second chimeric polypeptide” whereas step (A) recites “the first chimeric polypeptide”. It is still unclear whether the modulating substance is a mandatory component of the first fragment or merely one of the possible options for the first fragment.

Claims 10 and 25 are rendered vague and indefinite by the use of the phrase “wherein the signal triggers transcriptional activation and expression of a reporter gene”. It is unclear what is meant by said phrase. Is the “transcriptional activation” of the reporter gene that in turn leads to its expression or is said “transcriptional activation” not directly related to the expression of the reporter gene? As written, it is impossible to determine the metes and bounds of the claimed invention.

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Claims 46-47 and 52-53 are rendered vague and indefinite by the use of the term “protein involved in the catabolism of a nutritional marker”. It is unclear what Applicant is ~~claims~~^{claimed} since it is unclear what constitutes a “nutritional marker”. Moreover, it is unclear what constitutes an “involvement in catabolism”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 46-47 and 52-53 to recite, “encoding a protein involved in the catabolism of a nutritional marker”. This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Moreover, the portion of the Specification cited by Applicant relates to the activation of catabolic operons by cAMP. Therefore this limitation is new matter.

Claims 46-47 and 52-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a vast genus of gene fragments. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of antibodies, Applicant must adequately describe the biological function of said gene fragments.

However, the specification does not disclose distinguishing and identifying features of a representative number of members of the genus of polynucleotides to which the claims are drawn (including a fragment consisting of a single nucleic acid), such as a correlation between the structure of the polynucleotide and its recited function, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of gene fragments. Moreover, the specification fails to disclose which nucleic acid residues are essential to the function of the polynucleotide, or

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which nucleic acid residues might be replaced or deleted so that the resultant polynucleotide retains the activity of its parent. Therefore, the specification fails to adequately describe at least a substantial number of members of the genus of peptides to which the claims refer; and accordingly the specification fails to adequately describe at least a substantial number of members of the claimed genus of gene fragments.

MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed’ ”. The courts have decided:

The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, “Written Description” Requirement (66 FR 1099-1111, January 5, 2001) state, “[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was ‘ready for patenting’ such as by disclosure of drawings or structural chemical formulas that show that the invention was

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complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention” (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was “ready for patenting” by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus” (*Id.* at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of gene fragments is not deemed representative of the genus of peptides to which the claims refer.

Conclusion

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

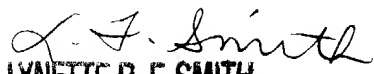
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
June 14, 2004


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